Revision of PRECAUTIONS

Imidafenacin

June 3, 2014

Non-proprietary Name
Imidafenacin

Safety measure
Precautions section should be revised in a package insert.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added (underlined parts are revised):

Hepatic dysfunction:

Hepatic dysfunction with elevations of aspartate aminotransferase (AST or glutamate oxaloacetate transaminase [GOT]), alanine aminotransferase (ALT or glutamate pyruvate transaminase [GPT]), or bilirubin may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.